HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Pharmaceutical Services Manual

Proposed Readoption with Amendments: N.J.A.C. 10:51

Authorized By: Gwendolyn L. Harris, Commissioner, Department of Human Services.

Authority: N.J.S.A. 30:4D-6, 7 and 12.

Calendar Reference: See Summary below for explanation of the exception to the rulemaking calendar requirements.

Agency Control Number: 03-P-10.

Proposal Number: PRN 2003-

Submit comments by October 17, 2003 **to:**

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The agency proposal follows:

Summary

Pursuant to N.J.S.A. 52:14B-5.1c, N.J.A.C. 10:51, the Pharmaceutical Services Manual, expires on February 24, 2003. This proposal is designed to readopt subchapters 10:51-1 through 3 of the Pharmaceutical Services Manual which continue to be relevant to the Division of Medical Assistance and Health Services (DMAHS).

An administrative review has been conducted, and a determination made that Subchapters 1 through 3 should be readopted with certain amendments, because the rules are necessary, reasonable, adequate, efficient, and responsive for the purposes for which they were promulgated.

This chapter on Pharmaceutical Services provides information about the provision of pharmaceutical services under the New Jersey Medicaid and the NJ FamilyCare fee-for-service (FFS) pharmacy benefit programs. As originally adopted, the manual was divided into four subchapters, Pharmaceutical Services, Pharmaceutical Services to Medicaid Beneficiaries in a Nursing Facility, Consultant Pharmacist, and Pharmaceutical Assistance to the Aged and Disabled Program (PAAD). The text of Subchapter 4, concerning PAAD is now under the authority of DHSS, and is contained in DHSS rules. Therefore, Subchapter 4 continues to be reserved for future use by the Division.

N.J.A.C. 10:51-1, Pharmaceutical Services, provides a pharmacy operating under a retail permit with notice of the policies and procedures relevant to the provision of services to New Jersey Medicaid/NJ FamilyCare beneficiaries, excluding those residing in a nursing facility. This subchapter provides an introduction to pharmaceutical services, participation

of eligible providers and conditions for participation as well as program restrictions. It also covers basis of payment, discounts, dispensing fees, compound and generic prescriptions, and the providers' advertised charge. The subchapter also lists the covered and non-covered pharmaceutical services, prior authorization requirements, quantity, dosage and direction for medication and personal contribution to care requirements for NJ FamilyCare-Plan C and copayment requirements for Plan D. Prescriptions, such as telephone-rendered original prescriptions, changes or additions to the original prescription, and refills are covered. Also described in this subchapter is the Prescription Drug Price and Quality Stabilization Act, Drug Efficacy Study Implementation (DESI), Drug manufacturers rebate agreement, and rules for bundled drug. The last sections provide the rules for claim submission, the Point-of-sale (POS) claims adjudication system and the State's Fiscal Agent for beneficiaries covered under a Managed Care Contract.

N.J.A.C. 10:51-2, Pharmaceutical Services to Medicaid Beneficiaries in a Nursing Facility, pertains to a pharmacy providing pharmaceutical services to beneficiaries in a Nursing Facility. This subchapter provides the rules for pharmaceutical services to Medicaid beneficiaries in a nursing facility, participation of eligible providers, and conditions for participation as well as program restrictions. It also covers the rules for basis of payment, discounts, dispensing fees, compound prescriptions, dosage and direction for medication and generic prescriptions. The subchapter lists the covered and non-covered pharmaceutical services to Medicaid beneficiaries in a nursing facility, prescriptions and inpatient medication orders rendered by telephone or technological devices, changes or additions to the original, and refills. Also described in this subchapter is the Prescription Drug Price and Quality Stabilization Act, Drug Efficacy

Study Implementation (DESI), Drug manufacturers rebate agreement, and bundled drug service. The last sections provide the rules for claim submission, Point-of-sale (POS) claims adjudication system and the Prospective Drug Utilization Review (PDUR) program.

N.J.A.C. 10:51-3, Consultant Pharmacy Services, provides an introduction to the services provided by a consultant pharmacist, the definition of a consultant pharmacist, as well as the qualifications required to fulfill the responsibilities of a pharmacist. Finally, the responsibilities of a pharmacist acting as a consultant in a nursing facility or other public medical institution are delineated.

Throughout the rules, references are made to the standards found in Version 5.1 and Version 1.1 of the National Council Prescription Drug Program (NCPDP) which have been incorporated by reference at N.J.A.C. 10:51-1.8(d), 1.24(a)2 and 3 and 2.21(a)2 and 3. The NCPDP creates data interchange standards for the pharmacies services sector of thehealth care industry. Version 1.1 is the Batch Transaction Standard, which provides guidelines and consistent implementation throughout the industry of a file submission standard. Version 5.1 supports point-of-sale (POS) claims processing used by pharmacists to request payment.

There are seven appendices contained in N.J.A.C. 10:51. Appendix A contains the drugs designated by the United States Food and Drug Administration, in accordance with 21 C.F.R. 310.6, as products that lack substantial evidence of effectiveness. Appendix B contains the drugs designated by the Centers for Medicare and Medicaid Services (CMS) as meeting the criteria contained in 42 C.F.R. § 447.301, 331, 332 and 333. Appendix C

is the most recent version of Form FD-70, the Division's Pharmacy Provider Certification Statement. Appendix D, the Fiscal Agent Billing Supplement, contains billing instructions for providers. Appendix E, Electronic Media Claims (EMC) Manual, contains instructions to providers regarding the submission of claims via electronic media. Appendix F is a list of drug manufacturers who have a rebate agreement established in accordance with 42 U.S.C. § 1396R-8(a), (b) and (c). Appendix G is an agreement form to be completed by pharmacies servicing nursing facilities in accordance with the requirements of N.J.A.C. 10:51-2.7.

Technical amendments

The proposed technical amendments to the chapter include:

Deletion of all references to the "Health Care Financing Administration (HCFA)" and substitution or addition of the words "Centers for Medicare and Medicaid Services (CMS)."

Throughout N.J.A.C. 10:51, the Division proposes changing all references from "NJ KidCare" to "NJ FamilyCare." The reasons for this name change are that when the rules implementing the NJ KidCare program (see 30 N.J.R. 713(a) and 3034(a) effective February 1, 1998), were adopted, text was added indicating that unless otherwise specified, all Medicaid program rules were equally applicable to NJ KidCare. Similarly, when the rules implementing NJ FamilyCare were concurrently proposed and adopted (see 32 N.J.R. 3603(a) and 33 N.J.R. 1126(a), effective March 5, 2001), the NJ KidCare

program was effectively combined with the NJ FamilyCare program, without changing the scope of the NJ KidCare program.

Throughout the chapter, references to "GA beneficiary" have been changed to "WFNJ/GA beneficiary."

At N.J.A.C. 10:51-1.2(d)1ii3, the Division has included the full program name for the acronym (PAAD), that is Pharmaceutical Assistance for the Aged and Disabled.

At N.J.A.C. 10:51-1.4(a)3 the Division has amended the subsection citation from N.J.A.C. 51-1.25 to N.J.A.C. 51-1.26, to reflect the proper Prospective Drug Utilization Review (PDUR) program subchapter citation**.**

At N.J.A.C. 10:51-1.7(a)3, the Division has added the full name of the PAAD program, that is, it has added the words “Pharmaceutical Assistance to the Aged/Disabled” before the acronym PAAD.

At N.J.A.C. 10:51-1.14(b)4, the Division is correcting a typographical error. “An orexiant” is being changed to “anorexiant” as this is the true and complete spelling of the word.

At N.J.A.C. 10:51-1.14(b)4v., the Division is adding the words “Work First New Jersey” to more accurately reflect the Work First New Jersey/General Assistance program’s proper name.

At N.J.A.C. 10:51-1.23 (c)1, the Division is correcting a mailing address.

At N.J.A.C. 10:51-1.25(f), the word “shall” is being added.

At N.J.A.C. 10:51-2.8(g)2, the words “must” and “is” are being changed to “shall.” Similarly, at N.J.A.C. 10:51-2.8(g)3 and 4, the words “must,” “is” and “are” have been changed to “shall.”

At N.J.A.C. 10:51-2.11(a), the word “are” is being changed to “shall.”

At N.J.A.C. 10:51-2.17(a)3, the Division is correcting a typographical error. The third reference to “prescriber” is being changed to “prescribed,” as this is the appropriate word to use when describing the action defined in this sentence.

At N.J.A.C. 10:51-2.20(c)1, the Division is correcting a mailing address.

At N.J.A.C. 10:51-2.21(b)1, the Division is correcting two typographical errors by changing the period after the reference to Appendix D to a comma, and adding a comma after “Appendix E.”

At N.J.A.C. 10:51-2.23(a), the Division is deleting the word “approved” and replacing it with “recommended” as this accurately describes the activity by the N.J. Drug Utilization Review Board being described.

The Division is proposing to readopt Appendices A, B, and D through F with technical changes where needed. References to "Unisys/Paramax" contained in these appendices have been changed to "Unisys," the Division's Fiscal Agent. Appendix C has been amended to reflect the most recent version of Form FD-70 (revised 10/02), the Division's Pharmacy Provider Certification Statement. The proposed amendments to the form concern adding reference to NJ FamilyCare, Aids Drug Distribution Program (ADDP), Cystic Fibrosis (CF), and Senior Gold Prescription Discount (SGPD) pharmacy programs.

Adding these text changes to N.J.A.C. 10:51 does not represent a change in Division policy, but simply revises the text to ensure accuracy in terminology and usage.

Substantive amendments

The proposed substantive changes are as follows:

At N.J.A.C. 10:51-1.8(d), the Division has added text to qualify that reimbursement for compounded prescriptions without proper active ingredients is to be based on the cumulative cost of the pharmaceutical excipients, unless otherwise specified by NCPDP standards, Version 5.1 and Version 1.1 as amended and supplemented and incorporated by reference. This proposed amendment also includes the addition of the National Council Prescription Drug Program's address, from where these standards may be obtained.

At N.J.A.C. 10:51-1.11(b)2, the Division is proposing adding a paragraph to clarify that in order for a brand name non-legend drug to be covered, the prescriber must document

"Brand Medically Necessary" on the prescription. Otherwise, only the generic non-legend product is covered.

At N.J.A.C. 10:51-1.11(e), the Division is proposing adding that atypical antipsychotics shall be reimbursed through the State's Fiscal Agent for beneficiaries covered under a Managed Care Contract.

At N.J.A.C. 10:51-1.11(f), the Division is proposing adding that beneficiaries are covered for anti-impotency drugs, but that the prescribed amount may not exceed more than four doses per month and that each prescription must include a diagnosis related to impotency.

At N.J.A.C. 10:51-1.14(b)6, the Division is proposing to increase the threshold in the volume of prescriptions which may be prescribed for beneficiaries from seven to 12 per month.

At N.J.A.C. 10:51-1.14(b)6iii, the Division is proposing to add categories of legend drugs which will not require prior authorization before dispensing. N.J.A.C. 10:51-1.14(b)6iii and iv have been recodified with no change in text.

At N.J.A.C. 10:51-1.14(b)6vi, the Division is proposing that prior authorization not be required for beneficiaries in the pharmacy lock-in program.

At N.J.A.C. 10:51-1.17(a), the Division is proposing adding the word “rules” to clarify that all relevant New Jersey rules, including, but not limited to Board of Pharmacy rules, must be followed when telephone orders from prescribers are received.

At N.J.A.C. 10:51-1.21(a)3, the Division is proposing substituting the word “identification” for the word “list” to more accurately describe what is actually contained in the Federal regulation being described in this rule.

At N.J.A.C. 10:51-1.24(a)2, the Division is amending this section to require an electronic format which complies with the National Council Prescription Drug Program (NCPDP) Version 5.1 and Version 1.1, standards, as amended and supplemented, incorporated herein by reference. The Council’s address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

At N.J.A.C. 10:51-1.24(a)3, the Division is proposing that a reference to Version 3.2 program standards of the National Council Prescription Drug Program (NCPDP) be deleted and that Version 5.1 and Version 1.1 be added, along with an incorporation by reference, so that the Division and its providers will be using the most recent version at all times as the Division will change the approved electronic formula based on future changes approved by the NCPDP..

At N.J.A.C. 10:51-1.25(g)3, the Division is adding text to include WFNJ/GA program prior authorization numbers, if applicable, in addition to Medicaid NJ FamilyCare prior authorization numbers, must be submitted by an approved pharmacy provider as additional

supplementary data, when the provider chooses to submit claims through the Point of Sale (POS) system.

At N.J.A.C. 10:51-1.25(l), the Division is adding text to provide that the procedures and provisions of this subsection for coverage of prescriptions provided to Medicaid/NJ FamilyCare beneficiaries during an interruption in POS service are likewise applicable to WFNJ/GA program beneficiaries.

At N.J.A.C. 10:51-1.26(c), the Division is adding three more PDUR standards (drug-gender conflicts, under-usage, and weight-based) which are currently applied to the automated POS review of prescriptions. They will be added to the notification the pharmacist receives regarding drug utilization of a beneficiary that is inconsistent with adopted PDUR standards. The Division is also proposing to amend N.J.A.C. 10:51-1.26(c)1 to read "Drug-drug interactions" rather than "Drug interactions," amending N.J.A.C. 10:51-1.26(c)2 by removing the word "alerts," and amending N.J.A.C. 10:51-1.26(c)4 by adding a hyphen to the category of "Drug-age conflicts" to make clear that it is the age of the beneficiary which will be considered in the utilization review. The Division is also proposing that at N.J.A.C. 10:51-1.26(c)6, the category "Drug-disease precautions" be deleted as there are no POS edits currently in use for this category.

At N.J.A.C. 10:51-2.2(b)3, the Division is proposing an amendment to add the letter "D" after the word Appendix to clarify that the applicable Appendix for this section is Appendix D.

At N.J.A.C. 10:51-2.8(g)2, 3, and 4, the Division is proposing to amend the rules to indicate the types of legend and non-legend ingredients which must be included in order for a compounded prescription to be reimbursable by the Medicaid/NJ FamilyCare programs.

At N.J.A.C. 10:51–2.18, the Division is proposing substituting the word “identification” for the words “list” to more accurately describe what is actually contained in the Federal regulation being described in this rule.

At N.J.A.C. 10:51-2.21(a)2, the Division is amending this section to require an electronic format which complies with the NCPDP standards Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference so that the Division and its providers will be using the most recent version at all times. The Council’s address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

At N.J.A.C. 10:51-2.21(a)3, the Division is proposing that the reference to Version 3.2 program standards of the National Council Prescription Drug Program (NCPDP) be deleted and replaced with Version 5.1 and Version 1.1. Further, the Division is changing N.J.A.C. 10:51-2.21(a)3 by adding the words “approved by the Division” prior to the reference to the electronic format which complies with the NCPDP standards as amended and supplemented.

At N.J.A.C. 10:51-2.23, the Division is proposing to add three more PDUR standards (drug-gender conflicts, under-usage, and weight-based) which are currently applied to the

automated POS review of prescriptions. They will be added to the notification the pharmacist receives regarding drug utilization that is inconsistent with adopted PDUR standards. The Division is also proposing to amend N.J.A.C. 10:51-2.23(c)1 to read "drug-drug interactions" rather than "drug interactions," N.J.A.C. 10:51-2.23(c)2 by removing the word "alerts," and 10:51-2.23(c)4 by adding a hyphen to the category of "drug-age conflicts" to make clear that it is the age of the beneficiary which will be considered in the utilization review. At N.J.A.C. 10:51-2.23(c)5, the Division is proposing to amend the category of "Days supply alerts" to "Duration of therapy." The Division is also proposing that at N.J.A.C. 10:51-2.23(c)6, the category "drug-disease precautions," be deleted as there are no POS edits currently in use for this category.

The Division is proposing to readopt Appendices A, B, and D through G with substantive and technical changes where needed. Appendix C has been updated to reflect the most recent version of Form FD-70 (revised 10/02), the Division's Pharmacy Provider Certification Statement. The proposed amendments to this form concern adding references to the NJ FamilyCare, Aids Drug Distribution Program (ADDP), Cystic Fibrosis (CF), and Senior Gold Prescription Discount (SGPD) pharmacy programs.

The Division is proposing amendments to Appendices A, B, D, E, and F by adding language that indicates changes to these appendices will be posted on the Medicaid web site, www.njmmis.com.

Social Impact

During State Fiscal Year 2002, an estimated 169,600 beneficiaries received prescriptions each month under the Medicaid program.

The rules proposed for readoption with amendments should have a positive impact on Medicaid and NJ FamilyCare fee-for-service beneficiaries since the rules will assure the continued coverage of pharmaceutical services to beneficiaries. The continued coverage of pharmaceutical services provided to individuals who might otherwise not be able to afford the medications should have a positive social impact on hospitals and publicly funded clinics that provide charity care because access to medications may alleviate or prevent the need for medical care for more acute symptoms of a medical disorder.

Economic Impact

The rules proposed for readoption with amendments should have a positive impact on pharmaceutical providers because they will continue to be reimbursed for services which customers might not otherwise be able to afford. During State Fiscal Year 2002, the Division spent approximately $526,229,619 (Federal and State combined) for approximately 7,016,395 prescriptions.

The rules proposed for readoption should not change annual expenditures, since they do not contain changes in eligibility, reimbursement or coverage. There are no costs to providers which are specifically associated with these rules, beyond the costs of maintaining records adequate for billing purposes. All requirements are contained in statute.

Federal Standards Statement

All references to "the Act" below refer to the Federal Social Security Act.

Sections 1902(a)(10), 1905(a)12 and 2110(a) of the Social Security Act (42 U.S.C. §§ 1396(a)(10), 1396d(a), and 1397jj respectively) allow a state Medicaid or NJ FamilyCare-Children's Program, at its option, to provide pharmaceutical services.

Federal regulations at 42 C.F.R. 440.120 define what may be covered as prescribed drugs. Federal requirements regarding restrictions on coverage are contained in Section 1927(d) of the Act (42 U.S.C. §1396r-8(d)). The option to establish a drug utilization review board or a formulary is included in Section 1927(g) (42 U.S.C. §§ 1396r-8(g)). Rebate requirements are contained in Sections 1927(a), (b), and (c) of the Act (42 U.S.C.§ 1396r-8(b)-(c)) and 1396 r-8(k) and 1927(k) respectively).

Federal restrictions regarding payment for less than effective drugs (known as DESI) are included in Section 1927(k) of the Act (42 U.S.C. § 1396r-8(k)(2)(A) and 21 C.F.R. 310.6. Drug rebate requirements are at Section 1927(a)-(c) of the Act (42 U.S.C.§§ 1396r-8(a)-(c).

Payment for drugs is subject to Federal upper payment limits (42 C.F.R. § 447.334) and Section 1927(e), (k) of the Act (42 U.S.C.§§ 1396r-8(e) and 8(k) respectively). The State

has defined the upper payment limits at N.J.A.C. 10:51-1.5, 2.5 and 4.5, Basis of payment.

Within the Federal requirements, the State has discretion to define its coverage, utilization control and review activities and its payment methodology, as long as it stays within the Federal limits.

The Division has reviewed the applicable Federal statutes and regulations and has determined that the rules proposed for readoption with amendments do not exceed Federal requirements.

Jobs Impact Statement

The Division anticipates that the rules proposed for readoption with amendments will not have an impact on employment in the State of New Jersey, and does not expect that any jobs will be gained or lost as a result of these rules.

Agriculture Industry Impact

The rules proposed for readoption with amendments will have no impact on the agriculture industry in the State of New Jersey.

Regulatory Flexibility Analysis

Although some pharmaceutical services providers may be considered small businesses under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14-16 et seq., the rules proposed for readoption with amendments contain only minimal additional recordkeeping, reporting or compliance requirements on providers. All providers, regardless of size, are required to maintain sufficient records to indicate the name of the patient, dates of service, nature, and any additional information as may be required by regulation. This requirement is part of N.J.S.A. 30:4D-12. Other requirements regarding reimbursement levels are contained in Federal Statute and regulation. There should be no need to hire any additional professional staff. The rules proposed for readoption with amendments do not impose requirements on providers regarding the hiring of professional staff beyond those imposed by State and Federal statutes, rules and regulations. Any capital costs incurred by a provider would be incurred in the normal course of business when operating a pharmacy, and would not be a result of this proposed rulemaking. The Division is not permitted by statute to differentiate between large and small businesses in the promulgation of these rules.

Smart Growth Impact

The Division anticipates that the rules proposed for readoption with amendments will have no impact on smart growth in New Jersey or on the implementation of the State Development and Redevelopment Plan.

Full text of the proposed readoption may be found in the New Jersey Administrative Code at N.J.A.C. 10:51.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets **[**thus**]**):

SUBCHAPTER 1 PHARMACEUTICAL SERVICES

10:51-1.1 Introduction

(a) This chapter provides information about the provision of pharmaceutical services under the New Jersey Medicaid program and **[**NJ KidCare**]** **NJ FamilyCare** program. It is divided into three subchapters.

1. N.J.A.C. 10:51-1 provides a pharmacy operating under a retail permit with the policies and procedures relevant to the provision of services to New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiaries, excluding those residing in a nursing facility.

2. – 3. (No change.)

(b) (No change.)

10:51-1.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program as a provider of pharmaceutical services; as a medical supplier providing medical supplies and durable medical equipment; and/or as a provider of parenteral nutrition and/or intravenous therapy. The

requirements for approval as a provider of these services are listed in (b) through (d) below.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the Board of Pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out-of-state institutional permit may not participate as an approved provider in the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program; and

2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

   i. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit (see N.J.A.C. 10:49 - Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(c) (No change.)

(d) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. (No change.)

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** program; however, billing for the ancillary supplies associated with parenteral nutrition and/ or intravenous therapy are subject to the requirements of the Medical Supplier Chapter (N.J.A.C. 10:59).

i. (No change.)

10:51-1.4 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable law. However, the prescriber's discretion is limited for certain

drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. - 2. (No change.)

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-**[1.25]** **1.26).**

4. - 11. (No change.)

12. Drug Manufacturers' Rebate Agreement with the **[**Health Care Financing Administration**]** **Centers for Medicare and Medicaid Services (CMS)** of the United States Department of Health and Human Services (see N.J.A.C. 10:51-1.22);

13. - 14. (No change.)

(b) If a prescription is not dispensed directly to the New Jersey Medicaid fee-for-service, **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service, or **Work First New Jersey/**General Assistance (**WFNJ/**GA) beneficiary for whom the prescription was written, and the claim charge exceeds $150.00, the individual picking up the prescription shall present the Medicaid Identification Card, the **[**NJ KidCare**]** **NJ FamilyCare** Identification Card or the authorized documentation confirming

WFNJ/GA eligibility of the beneficiary. Without the required proof of identity, the prescription shall only be dispensed in accordance with (b)1 and 2 below:

1. If the individual picking up the prescription cannot produce the beneficiary's eligibility documentation, then the non-beneficiary shall produce a valid driver's license as identification. Pharmacies shall record and maintain on file the driver's license number of the non-beneficiary picking up the prescription on the pharmacy signature log or a photocopy of the driver's license presented by the non-beneficiary. Payments for Medicaid fee-for-service or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service covered pharmacy services not dispensed directly to the beneficiary for whom there is no documentation or a photocopy of the driver's license of the non-beneficiary picking up the prescription shall be subject to full recovery by the State.

2. – 3. (No change.)

10:51-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend or non-legend drug for both the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs. The elements include the following:

1. - 2. (No change.)

3. Federal regulations (42 CFR 447.301, 331-334) set the aggregate upper limits on payment for certain covered drugs in the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** - Plan A pharmaceutical program. The Division applies the limits to **[**NJ KidCare**]** **NJ FamilyCare** - Plan**s** B and C. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. (No change.)

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the **[**Healthcare Financing Administration (HCFA)**]** **Centers for Medicare and Medicaid Services (CMS)** of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale

price (AWP) listed for the package size (billed to the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. - 3. (No change.)

(c) The maximum charge to the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

(d) The maximum allowance for protein replacement supplements, specialized infant formulas and food oils under the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** program is the lesser of:

1. - 2. (No change.)

(e) For claims with service dates on or after July 15, 1996, the maximum allowance for non-legend drugs (including protein replacement supplements, specialized infant formulas and food oils), devices, or supplies under the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program shall be calculated in accordance with (b)1ii above.

1. - 2. (No change.)

(f) (No change.)

10:51-1.7 Prescription dispensing fee

(a) The dispensing fee for legend drugs, dispensed by providers having retail permits to beneficiaries other than those in long-term care facilities, including State operated Intermediate Care Facilities/Mentally Retarded (ICFs/MR), nursing facilities and State and county operated long-term psychiatric hospitals, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-Four Hour Emergency Service: $0.11. The provider shall have a 24-hour per day, 365-days-per-year prescription service available and shall have provided Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiaries opportunities to utilize this service.

2. Patient Consultation: $0.08. In addition to routinely monitoring beneficiary profiles for drug interactions, contraindications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the beneficiary. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side

[affects**]** **effects**; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the beneficiary while on drug therapy.

3. Impact Area Location: $0.15. The provider shall have a combined Medicaid**[**, NJ KidCare**]/NJ FamilyCare**, and **Pharmaceutical Assistance to the Aged/Disabled (**PAAD**)** prescription volume equal to or greater than 50 percent of the provider's total prescription volume.

i. (No change.)

(b)-(d) (No change.)

10:51-1.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved pharmacy providers.

1. (No change.)

(b) - (c) (No change.)

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s)**, unless otherwise specified by NCPDP standards, Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.**

1. For pharmaceutical excipients costing less than $0.25, the provider may charge Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** $0.25 for each ingredient.

2. (No change.)

(e) - (f) (No change.)

(g) Restriction in payments for compounded prescriptions are as follows:

1. (No change.)

2. All non-legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51-1.11, the compounded prescription is not covered.

3. All legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service programs. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-1.20) drug, the compounded prescription is not covered.

4. (No change.)

10:51-1.10 Provider's usual and customary charge or advertised charge

(a) (No change.)

(b) The usual and customary charge to the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the programs more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid, **[**NJ KidCare**]** **NJ FamilyCare** and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the programs would reimburse for the same services.

10:51-1.11 Covered pharmaceutical services

(a) (No change.)

(b) Covered pharmaceutical services include:

1. (No change.)

2. In order for a brand name non-legend drug to be covered, the prescriber must document "Brand Medically Necessary" on the prescription. Otherwise, only the generic non-legend product is covered.

Recodify existing 2. - 3. as 3. – 4. (No change in text.)

(c) - (d) (No change.)

(e) For beneficiaries covered under a managed care contract, atypical antipsychotics shall be reimbursed through the State's fiscal agent.

(f) Anti-impotency drugs shall be covered not to exceed four doses per month. Each prescription must include a diagnosis related to impotency.

10:51-1.12 Personal contribution to care requirements for [NJ KidCare] NJ FamilyCare-Plan C and copayments for [NJ KidCare] NJ FamilyCare-Plan D

(a) General policies regarding the collection of personal contribution to care for **[**NJ KidCare**]** **NJ FamilyCare**-Plan C and copayments for **[**NJ KidCare**]** **NJ FamilyCare**-Plan D are set forth at N.J.A.C. 10:49-9.

(b) Personal contribution to care for **[**NJ KidCare**]** **NJ FamilyCare**-Plan C services are $1.00 per dispensing for generics and $5.00 per dispensing for brand name drugs. Included in drugs are insulin, needles and syringes.

(c) Pharmacies are required to collect the personal contribution to care for the above-mentioned **[**NJ KidCare**]** **NJ FamilyCare**-Plan C services if the **[**NJ KidCare**]** **NJ FamilyCare** Identification Card indicates that a personal contribution to care is required and the beneficiary does not have a **[**NJ KidCare**]** **NJ FamilyCare** form which indicates that the beneficiary has reached their cost share limit and no further personal contributions to care **[**is**]** **are** required, until further notice. Personal contribution to care charges cannot be waived.

(d) The copayment for prescription drugs under **[**NJ KidCare**]** **NJ FamilyCare**-Plan D shall be $5.00 per prescription:

1. (No change.)

(e) (No change.)

10:51-1.13 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service programs. For beneficiaries in the Medically Needy component of the New Jersey Care . . . Special Medicaid programs, pharmaceutical services are not available to the aged, blind nor the disabled who are residing in a long-term care facility (except a nursing facility) or in the community. For information on how to identify a covered person, see N.J.A.C. 10:49, Administration.

1. – 17. (No change.)

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. – 4. (No change.)

5. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid or**[**NJ KidCare**]** **NJ FamilyCare** program. (see N.J.A.C. 10:51-1.26).

(c) (No change.)

10:51-1.14 Services requiring prior authorization

(a) (No change.)

(b) The following drugs and specific therapeutic classes require prior authorization:

1. – 3. (No change.)

4. **[**An orexiants**]** **Anorexiants** and antiobesics when used for the treatment of conditions approved by the New Jersey State Board of Medical Examiners at N.J.A.C. 13:35-6.7;

5. (No change.)

6. Any prescription claim for the same beneficiary, provided within the same calendar month, that exceeds the monthly prescription volume threshold of **[**seven**]** **12** prescriptions per month. This applies whether the prescriptions were dispensed by one or more pharmacies. The need for prior

authorization shall be communicated to providers via the point of sale claims processing system. Prior authorization shall be requested as required by (a) above, except that prior authorization shall not be required in the following circumstances:

i. (No change.)

ii. Certain drugs and specific therapeutic drug classes including clozapine, antihemophiliac drugs, immunosuppressants, and HIV/AIDS drugs (limited to protease inhibitor, antiretroviral drugs, nucleoside analogs and reverse transcriptase inhibitors);

iii. Certain legend drugs, including oral contraceptives, ophthalmic preparations, otic preparations, nitroglycerin patches, vaginal preparations, and hemorrhoidal preparations;

[iii**.]iv.** Drugs otherwise requiring prior authorization in accordance with this subsection; **[**and**]**

[iv**.]v.** Drugs otherwise requiring prior authorization by the **Work First New Jersey/**General Assistance program**; and**

vi. Drugs dispensed to beneficiaries in the pharmacy lock-in program.

10:51-1.17 Telephone-rendered original prescriptions

(a) Telephone orders from prescribers for original prescriptions shall be permitted in accordance with all applicable Federal and State laws**, rules** and regulations.

(b) For purposes of reimbursement, telephone authorization to refill an original prescription with no refill remaining is considered a new order and requires a new written prescription with a new prescription number. Stamping or writing a new number on the original prescription order does not constitute a new prescription under the Medicaid or**[**NJ KidCare**] NJ FamilyCare** programs.

(c) - (d) (No change.)

10:51-1.20 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** accordingly.

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or **[**NJ KidCare**]** **NJ FamilyCare**.

3. For non-MAC drugs (see N.J.A.C. 10:51-1.5) when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51-1.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (see Appendix D, Fiscal Agent

Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format.)

2. (No change.)

b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** - Plan A may reimburse for certain multi-source drugs. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription (see N.J.A.C. 10:51-1.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a hand written statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs which have a Federal MAC limit. The Division shall also apply these Federal requirements to **[**NJ KidCare**]** **NJ FamilyCare**–Plans B and C.

(c) - (e) (No change.)

(f) The "Brand Medically Necessary" requirement for MAC prescriptions shall not apply for Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiaries enrolled in a

Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** participating Health Maintenance Organization (HMO).

10:51-1.21 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1.-2. (No change.)

3. The initial **[**list**]** **identification** of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions **[**to this list**]** which are adopted**[**,**]** shall appear in the Federal Register.

10:51-1.22 Drug manufacturers' rebate agreement

(a) In order for legend drug products to be reimbursed by the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program, manufacturers must have in effect a rebate agreement pursuant to Section 1927 et seq. of the Social Security Act (42 U.S.C. §1396R-8(i)).

(b) (No change.)

10:51-1.23 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program.

1. – 2. (No change.)

(c) In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, PO Box 712, Trenton, New Jersey 08625-0712.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiaries shall receive or continue to receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

[Medical Director**]** **Assistant Director**

Office of Utilization Management

Division of Medical Assistance and Health Services

Mail Code #**[**14**]** **15**

P.O. Box 712

Trenton, NJ 08625-0712

10:51-1.24 Claim submission

(a) An approved pharmacy provider may choose to:

1. (No change.)

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an **approved** electronic format **[**approved by DMAHS**]** **which complies with the National Council Prescription Drug Program (NCPDP) standards, Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.**

   i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid**[**,**]** or **[**NJ KidCare**]** **NJ FamilyCare** **[**and/or PAAD**]** programs, a pharmacy provider or vendor of EMC services

shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. - iv. (No change.)

2. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format which **approved by the Division** which complies with the National Council Prescription Drug Program standards, Version **[**3.2**]** **5.1 and Version 1.1,** as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** prescription dispensed. See Appendix D, Fiscal Agent Billing Supplement for instructions concerning the completion

and submission of the specified claim form, and Appendix E regarding the proper EMC claim format:

2. (No change.)

3. All Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

10:51-1.25 Point-of-sale (POS) claims adjudication system

(a) Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

(b) In order for a Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** approved pharmacy provider, in accordance with N.J.A.C. 10:51-1.3, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1. - 2. (No change.)

3. The Division shall consider the following in evaluating an application:

i.-iv. (No change.)

v. The applicant's adherence to the requirements of the **[**Health Care Financing Administration**]** **Centers for Medicare and Medicaid Services**.

(c) - (d) (No change.)

(e) All Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** pharmacy providers choosing to submit claims through the POS system, shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. (No change.)

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiary's first name;

2. The 12-digit Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** identification number;

3. - 8. (No change.)

9. The prescriber's Medicaid **or [**NJ KidCare**] NJ FamilyCare** provider service number;

10. - 12. (No change.)

(g) Additional supplementary data requirements, which are claim specific, shall include:

1. - 2. (No change.)

3. The Medicaid**,** **[**or NJ KidCare**]** **NJ FamilyCare or WFNJ/GA** prior authorization number, if applicable;

4. – 6. (No change.)

(h) - (i) (No change.)

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.

1. (No change.)

2. Pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiary.

3. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiaries properly documented on a **[**NJ KidCare**]** **NJ FamilyCare** approved certification statement/signature log. (See N.J.A.C. 10:49-9.6).

(k) (No change.)

(l) The following shall apply for coverage of prescriptions when provided to Medicaid/NJ FamilyCare **or Work First New Jersey/General Assistance (WFNJ/**GA**)** beneficiaries during an interruption in POS service:

1.– 6. (No change.)

10:51-1.26 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with monitoring drug utilization by Medicaid and **[**NJ KidCare**]NJ FamilyCare** fee-for-service beneficiaries. As a component of the **[**Medicaid/NJ KidCare**]** **Medicaid/NJ FamilyCare** point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real time regarding utilization within PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board, and approved by the Commissioner of the Department of Human Services (DHS) and the Commissioner of the Department of Health and Senior Services (DHSS). Similar responses related to EMC or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. – 2. (No change.)

(b) (No change.)

(c) In addition to POS responses related to adjudication of Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug**-drug** interactions;

2. Maximum/minimum daily dosage **[**alerts**]**;

3. (No change.)

4. Drug**-**age conflicts;

5. (No change.)

[6. Drug-disease precautions; and**]**

[7.**]** **6.** Drug-pregnancy precautions**;**

7. Drug-gender conflicts;

8. Under-usage; and

9. Weight-based.

(d) The PDUR program may apply adopted standards based on a severity index recommended by the New Jersey DUR Board to determine appropriate pharmacist intervention and/or claim disposition (that is, payment or denial) of Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims. (See N.J.A.C. 10:51-1.27.)

(e) - (f) (No change.)

10:51-1.27 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after September 1, 1999, which exceed PDUR standards recommended by the New Jersey DUR Board and approved by the Commissioners of DHS and DHSS, the Division of Medical Assistance and Health Services has established a medical exception process (MEP) for Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmaceutical services.

(b) - (c) (No change.)

(d) The medical exception process is as follows:

1. – 5. (No change.)

6. Claims subject to the medical exception process which have exhausted the 30-day allowance period and for which prior authorization has not been issued by the MEP contractor shall be denied payment by the **[**Medicaid/NJ KidCare**]** **Medicaid/NJ FamilyCare** programs.

SUBCHAPTER 2 PHARMACEUTICAL SERVICES TO MEDICAID OR [NJ KIDCARE] NJ FAMILYCARE FEE-FOR-SERVICES BENEFICIARIES IN A NURSING FACILITY

10:51-2.1 Introduction

This subchapter provides information about the provision of reimbursable pharmaceutical services provided to Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiaries in Medicaid approved nursing facilities.

10:51-2.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid and **[**NJ KidCare/NJ FamilyCare**]** **NJ FamilyCare** programs as a provider of pharmaceutical services, and as a provider of parenteral nutrition or intravenous therapy. The requirements for approval as a provider of pharmaceutical services are listed in (b) and (c) below.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the board of pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out-of-State institutional permit may not participate as an approved provider in the New Jersey Medicaid or **[**NJ KidCare**] NJ FamilyCare** program; and

2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

   i. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the New Jersey Medicaid and **[**NJ KidCare/Family Care**] NJ FamilyCare** programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit. (see N.J.A.C. 10:49 - Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit. (see Appendix **D**, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and **[**NJ KidCare/FamilyCare**] NJ FamilyCare** provider of pharmaceutical services, a pharmacy shall contact the fiscal

agent Provider Enrollment Unit (see Appendix **D**, Fiscal Agent Billing Supplement).

(b) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. (No change.)

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid or **[**NJ KidCare/FamilyCare**]NJ FamilyCare** program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter, N.J.A.C. 10:59.

i. (No change.)

(d) Any new pharmacy, or any purchaser of an existing pharmacy possessing a valid permit described in (b)1 above, that has applied for approval as a provider of pharmaceutical services in the Medicaid**, [**and/or NJ KidCare/FamilyCare**] NJ FamilyCare** and**/or WFNJ/**GA FFS programs may also apply for issuance of a temporary provider number. The temporary provider number, if issued by DMAHS, shall be effective on the date of issuance of the pharmacy permit, and shall be valid for up to 90 days. The temporary provider number may be utilized

for the sole and limited purpose of accessing the point-of-sale system in order to determine whether Medicaid or **[**NJ KidCare/FamilyCare**]** **NJ FamilyCare** claims would be payable if the pharmacy is subsequently approved for provider status. However, no payments shall be made unless the application for provider status is approved and a permanent provider number is issued.

(e) (No change.)

10:51-2.4 Program restrictions affecting payment of prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. - 2. (No change.)

3. Pharmaceutical services requiring pharmacist intervention as part of the **[**Medicaid/NJ KidCare**]** **Medicaid/NJ FamilyCare** prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-2.23);

4. - 13. (No change.)

10:51-2.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend drug. The elements include the following:

1. - 2. (No change.)

3. Federal regulations (42 CFR 447.301, 331-334) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs refer**[**s**]** to these upper limits as the "maximum allowable cost" (see (b) below); and

4. (No change.)

(b) Payment for legend drugs, contraceptive diaphragms, and reimbursable legend devices, is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See Appendix B for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the **[**Health Care Financing Administration (HCFA)**]** **Centers for**

Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. – 3. (No change.)

(c) – (e) (No change.)

10:51-2.7 Prescription dispensing fee (capitation)

(a) The New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs capitate the dispensing fee for each prescription for beneficiaries in Medicaid approved nursing facilities in accordance with the total number of Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiary days in the facility(ies) serviced by the pharmacy. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following levels of services: Pharmacies with institutional permits shall be reimbursed as defined in (a) above, except that the

daily per beneficiary capitation fee shall be 75 percent of the fee for pharmacies with retail permits.

1. – 4. (No change.)

(c) (No change.)

(d) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the services(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program determines that the provider was not entitled to reimbursement for them.

(d) (No change.)

10:51-2.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved providers.

1. (No change.)

(b) - (c) (No change.)

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s).

1. For pharmaceutical excipients costing less than $0.25, the provider may charge Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** $0.25 for each ingredient.

2. (No change.)

(e) - (f) (No change.)

(g) Restrictions on payments for compounded prescriptions are as follows:

1. (No change.)

2. All non-legend ingredients which are contained in compounded prescriptions **[**must**]** **shall** be **among those** covered by the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51-2.10, the compounded prescription **[**is**]** **shall** not **be** covered.

3. All legend ingredients which are contained in compounded prescriptions **[**must**]** **shall** be **among those** covered by the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-2.18) drug, the compounded prescription **[**is**]** **shall** not **be** covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-2.11 **[**are**]** **shall** not **be** covered.

10:51-2.11 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions **[**are**]** **shall** not **be** covered under the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program:

1. - 16. (No change.)

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. - 3. (No change.)

4. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs. (See N.J.A.C. 10:51-2.23)

10:51-2.14 Prescriptions and in-patient medication orders rendered by telephone or technological devices

(a) (No change.)

(b) For purposes of reimbursement, a telephone rendered and/or a technologically transmitted (for example: Fax) authorization to refill an original prescription is considered a new prescription or in-patient medication order and requires a new prescription number. Stamping or writing a new number on the original prescription or in-patient medication order does not constitute a new prescription under the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program.

(c) - (d) (No change.)

10:51-2.17 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription or in-patient medication order for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** accordingly.

2. When the prescriber initials "Substitution Permissible" on the prescription blank, the pharmacist shall dispense and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare**, as appropriate, for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or **[**NJ KidCare**]** **NJ FamilyCare**.

3. When a prescriber authorizes, in accordance with (b) below, the dispensing of a brand MAC drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or **[**NJ KidCare**]** **NJ FamilyCare**, as appropriate, for the **[**prescriber**]** **prescribed** product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51-2.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (See Appendix D, Fiscal Agent Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format).

4. (No change.)

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** - Plan A may reimburse for certain multi-source drugs. This limit shall also apply to **[**NJ KidCare**]** **NJ FamilyCare** – Plans B and C. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or in-patient medication order or follow-up written prescription or in-patient medication order to a telephone rendered prescription or technologically transmitted, (for example, Fax) (see N.J.A.C. 10:51-2.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check

off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a hand written statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs which have a Federal MAC limit.

(c) - (e) (No change.)

10:51-2.18 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. - 2. (No change.)

3. The initial **[**list**]** **identification** of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions **[**to this list**]** which are adopted, shall appear in the Federal Register.

10:51-2.19 Drug manufacturers' rebate agreement

(a) In order for legend drug products to be reimbursed by the New Jersey Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program, manufacturers must have in effect a rebate agreement pursuant to Section 4401 of OBRA 1990 and Section 1927 et seq. of the Social Security Act.

(b) (No change.)

10:51-2.20 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the **[**New Jersey**]** Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** program.

1. – 2. (No change.)

(c) In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, P.O. Box 712, Trenton, New Jersey 08625-0712.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, **[**New Jersey**]** Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiaries shall receive or continue to receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

[Medical Director**]** **Assistant Director**

Office of Utilization Management

Division of Medical Assistance and Health Services

Mail Code #**[**14**]** **15**

P.O. Box 712

Trenton, NJ 08625-0712

10:51-2.21 Claims submission

(a) Based on the level of service provided by an approved pharmacy to a nursing facility, a provider may choose to:

1. (No change.)

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an **approved** electronic format **[**approved by DMAHS**] that complies with the National Council Prescription Drug Program (NCPDP) standards, Version 5.1 and Version 1.1, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.**

i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid**[** ,NJ KidCare,**]** and/or **[**PAAD**]** **NJ FamilyCare** programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. - iv. (No change.)

3. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an **approved** electronic format which complies with the National Council Prescription Drug Program standards, **[**Version 3.2**]** **Version 5.1 and Version 1.1,** as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

4. (No change.)

(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** prescription dispensed. See Appendix D**[**.**]**, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form, and Appendix E**[**.**]**, regarding the proper EMC claim format;

2. (No change.)

3. All Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

10:51-2.22 Point-of-sale (POS) claims adjudication system

(a) (No change.)

(b) In order for a Medicaid or **[**NJ KidCare-approved**]** **NJ FamilyCare-approved** pharmacy provider, in accordance with N.J.A.C. 10:51-2.3, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1.- 3. (No change.)

(c) A POS participating pharmacy or intermediary shall supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the New Jersey Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** programs.

(d) (No change.)

(e) All Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** pharmacy providers choosing to submit claims through the POS system shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. (No change.)

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** beneficiary's first name;

2. The 12-digit Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** identification number;

3. – 14. (No change.)

(g) – (i) (No change.)

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.

1. (No change.)

2. Pharmacies are required to initiate claim reversals for those services in which the claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service beneficiary.

(k) (No change.)

10:51-2.23 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with monitoring drug utilization by Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** beneficiaries. As a component of the Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards **[**approved**]** **recommended** by the **[Medicaid]** **New Jersey.** Drug Utilization Review (DUR) Board. Similar responses related to EMC or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. (No change.)

2. PDUR standards adopted by the **[Medicaid]** **New Jersey** Drug Utilization Review (DUR) Board shall be applied to all Medicaid and **[**NJ KidCare**]** **NJ FamilyCare** pharmacy claims resulting from traditional pharmacy services provided in nursing facilities, regardless of the mode of claim submission.

(b) (No change.)

(c) In addition to POS responses related to adjudication of Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug**-drug** interactions;

2. Maximum/minimum daily dosage **[**alerts**]**;

3. (No change.)

4. Drug**-**age conflicts;

5. **[**Days supply alerts**]** **Duration of therapy**;

[6. Drug-disease precautions; and**]**

[7.**]** **6.** Drug-pregnancy precautions**;**

7. Drug-gender conflicts;

8. Under-usage; and

9. Weight-based

(d) The PDUR program may apply adopted standards based on **a** severity index approved by the **[**Medicaid**]** **New Jersey** DUR Board to determine appropriate pharmacist intervention and/or claim disposition (for example, payment or denial) of Medicaid or **[**NJ KidCare**]** **NJ FamilyCare** fee-for-service pharmacy claims.

(e) - (f) (No change.)

APPENDIX A

DRUG EFFICACY STUDY IMPLEMENTATION (DESI)

(Update of Drug Products and Known Related Drug Products that Lack Substantial Evidence of Effectiveness)

Appendix A is a list of drugs that the Food and Drug Administration (FDA) has proposed to withdraw from the market **[** which**]. The list** is updated periodically by the **[**Health Care Financing Administration**]** **Centers for Medicare and Medicaid Services** subsequent to published listing changes in the Federal Register, in accordance with 21 C.F.R. 310.6.

AGENCY NOTE: **[**The**]** Appendix A is filed as a part of this chapter/manual**,** but is not reproduced in the New Jersey Administrative Code. When revisions are made to **[**the**]** Appendix A, replacement pages will be distributed to providers**, placed on the web site at www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of **[**the**]** Appendix A, write to:

[Paramax/ Unisys**]** **Unisys**
P.O. Box 4801
Trenton, New Jersey 08650**-4801**

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
P.O. Box 049
Trenton, New Jersey 08625**-0049**

APPENDIX B

UPPER PAYMENT LIMITS FOR MAXIMUM ALLOWABLE COST (MAC) DRUGS

Appendix B lists the multiple source drugs which meet the criteria set forth in 42 CFR 447.301, 331-333 which is updated periodically by the **[**Health Care Financing Administration**]** **Centers for Medicare and Medicaid Services** subsequent to published listing changes in the Federal Register.

AGENCY NOTE: **[**The**]** Appendix B is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to **[**the**]** Appendix B, replacement pages will be distributed to providers**, placed on the web site at www.njmmis.com** and copies will be filed with the Office of Administrative Law.

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P.O. Box 049
Trenton, New Jersey 08625**-0049**

APPENDIX C
STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
AND
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PHARMACY PROVIDER CERTIFICATION STATEMENT

Pharmacy Name_____ Provider ID _____
Address _____
_____ Telephone (____)_____

SECTION I. FEE INCREMENTS ADDED TO BASIC DISPENSING FEE

1. Impact Allowance..... $0.15

This provider has a combined Medicaid/**NJ FamilyCare/**PAAD**/ADDP/CF/SGPD** prescription volume (including LTCF Rxs) equal to or greater than 50% of the total Rx volume and qualifies for "Impact Allowance."

Actual Percentage: _____ ____ Yes ____ No

Note: If conditions for earning impact allowance change, the provider must notify Unisys, in writing, at PO Box 4804, Trenton, NJ 08650-4804, within 30 days of change, and must immediately cease adding the impact allowance increment to the basic dispensing fee. If the State determines that the provider has not met the impact allowance requirements, the State shall recover the total reimbursement for this increment, retroactive to the date of this Statement.

2. 24-Hour Emergency Service..... $0.11

Provider certifies availability of 24 hours/day, 365 days/year prescription service
____ Yes ____ No

If yes, identify below the method used by your pharmacy to post notification of this service.

____ Window Sign ____ Prescription Counter Sign
____ Other Note: If "Other" is checked, please attach a complete description of the notification method used by your pharmacy notifying beneficiaries of this service.

24-Hour Emergency Service Telephone Number (____)_____
The 24-Hour Emergency Service Telephone Number must be a local call for beneficiaries serviced by your pharmacy. Failure to provide this number will result in the return of this form.

Note: If a provider discontinues 24-hour emergency service, **[**Unisys must be notified**]** **the provider must notify Unisys**, in writing, at PO Box 4804, Trenton, NJ 08650-4804 within 72 hours of this decision, and must immediately cease adding the increment to the basic dispensing fee.

3. Patient Consultation..... $0.08

Provider agrees to monitor all Medicaid**[** and **]/NJ FamilyCare/**PAAD**/ADDP/CF/SGPD** patient profiles, in accordance with New Jersey State Board of Pharmacy regulations (N.J.A.C. 13:39-7.14), and those requirements described by the Omnibus Budget Reconciliation Act (OBRA) of 1993. These requirements include, but are not limited to, offers to consult with beneficiaries concerning proper drug administration/storage, and potential drug interactions/conflicts identified by reviews of patient profiles, or as advised by the State's Point of Sale (POS)/Prospective Drug Utilization Review (PDUR) claims processing system. ____ Yes ____ No

SECTION II. OWNERSHIP DISCLOSURE STATEMENT

1. _____ Pharmacy Name

Chain Pharmacy ____ Yes ____ No

If yes, please indicate the number of pharmacies operating in the State of New Jersey:_____.

2. Does any person in your organization currently own or have an interest in or any relationship with any other corporation, partnership, or other organization providing services under the New Jersey Medicaid, **NJ FamilyCare,[** or **]**PAAD, **ADDP, CF or SGPD** programs?____ Yes ____ No

If yes, please explain such affiliations on a separate page and attach to the Certification Statement.

3. Indicate the legal status of your organization below.

_____ Sole Proprietor _____ Partnership _____ Non-Profit Corporation
_____ For-Profit Corporation _____ Government _____ Other (Specify) _____.

List names, professional degrees, home addresses, and percentage of ownership for all partners, directors, officers, and/or stockholders, as applicable:

NAME	DEGREE	HOME ADDRESS	% OWNERSHIP
1.			
2.			
3.			
4.			
5.			

I HAVE READ THE PHARMACY PROVIDER CERTIFICATION STATEMENT AND AGREE TO THE TERMS AND CONDITIONS SET FORTH HEREIN. I UNDERSTAND THAT THE MAXIMUM CHARGE TO THE STATE OF NEW JERSEY FOR ALL MEDICAID**, [**AND**] NJ FAMILYCARE,[** or **]**PAAD, **ADDP, CF AND SGPD** PRESCRIPTIONS FOR COVERED DRUGS AND RELATED PHARMACEUTICAL PRODUCTS/DEVICES MAY NOT EXCEED THE PRICING POLICIES OF THE STATE AS DESCRIBED IN N.J.A.C. 10:51-**[**1.5**]1.7** AND N.J.A.C. **[**10:51-4.5**]8:83C-1**.

Legal Signature of Principal: _____ Date:_____
Print Name: _____
Title:_____
Pharmacy Name: _____

NOTE: ALL **[**OF THE ABOVE-MENTIONED**]** STATEMENTS **IN THIS CERTIFICATION** ARE SUBJECT TO AUDIT AND REVIEW BY THE NEW JERSEY DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES (DMAHS) AND/OR THE NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES (DHSS), THEIR CONTRACTORS, OR OTHER STATE AND FEDERAL AGENCIES.

AFFIX
PHARMACY LABEL
HERE

FD-70 (REV. **[**11/97**]10/02**)

APPENDIX D

FISCAL AGENT BILLING SUPPLEMENT

AGENCY NOTE: The Fiscal Agent Billing Supplement is filed as an incorporated appendix of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Fiscal Agent Billing Supplement, replacement pages will be distributed to providers, **placed on the web site at www.njmmis.com** and copies will be filed with the Office of Administrative Law.

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Quakerbridge Plaza, Building 9
P.O. Box 049
Trenton, New Jersey 08625-**0049**

APPENDIX E

EMC MANUAL

AGENCY NOTE: The Electronic Media Claims (EMC) Manual is filed as an incorporated Appendix of this chapter**/**manual, but is not reproduced in the New Jersey Administrative Code. When revisions are made to the EMC Manual, replacement pages will be distributed to providers**, placed on the web site at www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of the EMC Manual, write to:

[Paramax/Unisys**] Unisys**
P. O. Box 4801
Trenton, N.J. 08650-4801

APPENDIX F

MEDICAID REBATE PROGRAM MANUFACTURERS' LABELER CODE LIST

Appendix F is a list of drug manufacturers, identified by labeler code, whose drug products are covered by the New Jersey Medicaid and NJ FamilyCare fee-for-service programs. These drug manufacturers have in effect a rebate agreement pursuant to 42 U.S.C. § 1396-r-8(a)(b) and (c). This list is updated periodically by the **[**Health Care Financing Administration**] Centers for Medicare and Medicaid Services** subsequent to published listing changes in the Federal **[**register**]Register**.

AGENCY NOTE: **[**The**]** Appendix F is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to **[**the**]** Appendix F, replacement pages will be distributed to providers**, placed on the web site at www.njmmis.com** and copies will be filed with the Office of Administrative Law.

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P.O. Box 4801
Trenton, New Jersey 08650**-4801**

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
P.O. Box 049
Trenton, New Jersey 08625**-0049**

Gwendolyn L. Harris, Commissioner
Department of Human Services

Date